Vitamin D Repletion in SLE Requires 2,000 IU

VITALS

Major Finding: Five of six black lupus patients who were given 2,000 IU vitamin D daily repleted serum 25-hydroxyvitamin D to 30 ng/mL or more at 3 months.

Data Source: A phase 1 study of 18 subjects.

Disclosures: The study was funded by the National Institutes of Health. The principal investigator said she had no disclosures.

BY M. ALEXANDER OTTO

FROM THE INTERNATIONAL CONGRESS ON SYSTEMIC LUPUS ERYTHEMATOSUS

VANCOUVER, B.C. — A daily dose of at least 2,000 IU of vitamin D is required to elevate serum 25-hydroxyvitamin D levels above 30 ng/mL, the minimum threshold for optimal immune health, according to Dr. Diane Kamen, a rheumatologist at the Medical University of South Carolina in Charleston.

The conclusion is based on an open-label, phase I study of vitamin D repletion in 18 black patients with lupus presented by Dr. Kamen.

Starting from a baseline mean 25-hydroxyvitamin D (25[OH]D) level of 13.3 ng/mL, six patients received 800 IU vitamin D once daily; six received 2,000 IU once daily; and six received 4,000 IU once daily.

After 12 weeks, 67% (four patients) in the 800 IU group, 83% (five) in the 2,000 IU group, and 67% (four) in the 4,000 IU group repleted to 30 ng/mL or greater.

In the 4,000 IU group, levels in 33% (two patients) rose above 40 ng/mL. That level was not reached at the lower doses.

The results are important, Dr. Kamen said in an interview after the conference, because although there is growing awareness that such high doses of vitamin D are needed to restore 25(OH)D levels in patients with autoimmune disease, the rheumatology literature still contains recommendations for doses of 600-800 IU/day.

"That's just not going to cut it; 2,000 IU a day is the minimum effective dose for repletion," especially if patients avoid the sun to prevent lupus flares, Dr. Kamen said.

Physicians "need to know to recommend those higher doses, and to monitor levels" of 25(OH)D to make sure they are maintained, she said.

The 18 patients were enrolled from a population of blacks living on the Sea Islands of South Carolina and Georgia, a population known as the Gullah in whom there is a high incidence of lupus.

An earlier Gullah study found that 43% of 187 subjects had 25(OH)D levels below 10 ng/mL; in some, levels were undetectable. Lower levels correlated with higher SLEDAI (Systemic Lupus Erythematosus Disease Activity Index) scores and higher anti-dsDNA antibody levels, Dr. Kamen said.

The mean age in the phase I study was 44 years; mean prednisone dose 4.3 mg/day; and mean SLEDAI score 2.4. In all, 17 of 18 of the subjects were women, 50% (9) took hydroxychloroquine, and 50% (9) were anti-dsDNA antibody positive. Compliance with the treatment regimen was 99%, by pill count. The doses were very well tolerated and safe.

Although 2,000 IU per day elevated 26(OH)D levels in most patients to at least 30 ng/mL, there's debate in the rheumatology community about whether target blood levels should be higher in lupus patients.

"We know that 30 ng/mL is the minimum accepted as normal," she said, noting that secondary hyperparathyroidism can begin below that level.

"We also know [healthy] sun-exposed people tend to live closer to 60 ng/mL. The debate is over if the target should be 30, 40, 50, or 60," she said.

"I tell my patients at high risk for conditions influenced by vitamin D, such as osteoporosis and inflammatory conditions, that we want them to stay between 40 and 60 ng/mL," she said, but "it's a gray zone" that awaits further research.

Levels of 25(OH)D are known to be low in lupus patients, but no one can say for sure whether that is a cause or a consequence of the disease, or if it results from the medications used to treat it, such as prednisone and hydroxychloroquine. ■

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AS DIABETES PROGRESSES, OADs ALONE MAY NOT BE ENOUGH

According to the UKPDS, up to 50% of β-cell function may be lost by the time patients are diagnosed with type 2 diabetes, and it may continue to decline, on average, by about 5% annually.[1] A recent article by DeFronzo showed that, in patients with highly impaired glucose tolerance, as much as 80% of β-cell function may be lost by the time of diagnosis.[2] It is this progressive β-cell function loss that is primarily responsible for the development of diabetes and the incremental rise in A1C.[2]

Patients may not know that their pancreas is no longer making enough insulin and that their disease has progressed.[3,4] National data from 2003 to 2004 showed that about 40% of patients with diabetes did not have adequate glycemic control.[5,a] And because blood glucose control is important, all available therapeutic options—including insulin—should be considered in the treatment of diabetes.

Many patients with type 2 diabetes may eventually need insulin to achieve or maintain glycemic control.[3,6]

Patients may blame themselves for what they perceive as 'failure' to control their glucose levels.[3] And because patients' attitudes toward their disease play an important role in diabetes self-care behaviors, it's likely that this negative mindset may adversely impact diabetes self-management.[7]

[a] Defined as A1C <7%.
OADs=oral antidiabetic drugs; UKPDS=United Kingdom Prospective Diabetes Study.

A POSITIVE "INSULIN TALK" MAY HELP REASSURE PATIENTS

The results of having a positive insulin talk can be impactful: in a survey, about 80% of patients with type 2 diabetes who were taking OADs said they'd consider taking insulin if their doctor recommended it.[8]

By starting the dialogue now, you can help your patients have a better understanding of insulin and the glucose-lowering role it plays as part of an overall diabetes treatment plan, which may include diet, exercise, and other diabetes medications.[3,9]

For appropriate patients, starting insulin earlier in the disease continuum can help improve glycemic control.[7,9-11] Insulin is an effective medication for lowering blood glucose levels.

So, engage patients in talks early and as needed to help turn their negative mindset of failure into a positive opportunity to manage their blood glucose.

Insulin is indicated to help improve glycemic control in patients with diabetes mellitus.

Treatment plans and glycemic targets should be individualized for each patient.

IMPORTANT SAFETY INFORMATION ABOUT INSULIN

Possible side effects may include blood glucose levels that are too low, injection site reactions, and allergic reactions, including itching and rash. Other medications and supplements could change the way insulin works. Glucose monitoring is recommended for all patients with diabetes.

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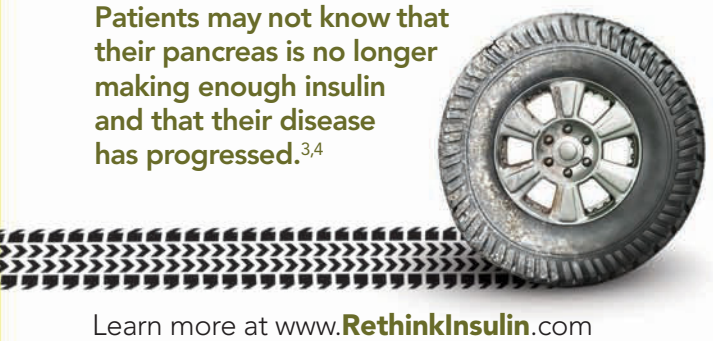

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INSULIN

IMPROVING BLOOD GLUCOSE CONTROL SHOULDN'T WAIT

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